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IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF OREGON

PORTLAND DIVISION

LEE WALTERS, MD, an Oregon resident, **Plaintiff**, v. **VITAMIN SHOPPE INDUSTRIES, INC.**, a Delaware corporation, **Defendant**.	Case No. 3:14-cv-01173-PK **PLAINTIFF'S OBJECTIONS TO FINDINGS AND RECOMMENDATIONS**

OBJECTIONS

1. The FDA warning letters from Defendant, and relied upon by the Court do not support Defendant's position or that reached by the Court, nor do they support dismissal of this action.

Defendant has presented, and the court has relied upon a series of FDA warning

letters for dismissal of this case. These cherry-picked examples simply show that one way to run afoul of the FDA's supplement labeling requirements is where the product contains different size portions or units that are not accurately represented on the Principal Display Panel. Nowhere do these warning letters assert or contain language showing that it is acceptable to place a statement of the number of units (i.e. 60 soft chews) AND pair that with an *inaccurate statement* of the quantity of supplement in each of those units (i.e. 1000 mg).

The examples cited by defendant do not overcome the plain language of the regulation that requires the Principal Display Panel to *accurately* display a "declaration of the net quantity of contents." Instead, at best the examples presented by Defendant and relied upon by the Court arguably show that where each unit contains the exact or nearly exact quantity of ingredient (as with the products at issue here), a manufacturer can simply state the number of units (or capsules or chews), and omit the statement of the weight or measure of supplement in each individual unit (or capsule or chew). Presumably, when that occurs the purchaser can search for the quantity of supplement contained in each unit, and find it on the Supplemental Facts panel on the back side of the package.

That, however, is not the issue in this case. Defendant has not taken that approach with any of the accused products. Instead, the Principal Display Panel for each of the products at issue in this lawsuit contain BOTH the number of units (or capsules or chews), AND Defendant then pairs that with an *inaccurate statement* of quantity (weight or measure) contained in each individual unit (or capsule or chew).

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Put another way, Defendant (and the court below) would be correct, the warning letters would be relevant, and there would be no basis for this lawsuit if the Principal Display Panel for each of the accused products simply listed the number of units (or capsules or chews) and nothing else. Instead, Defendant here took it one step further, and decided to include additional information that is allowed by the FDA regulations (weight or measure), but did so by providing an *inaccurate statement* of supplement quantity on the Principal Display Panel. That is what this case is about. It is not about, as Defendant argued and the Court found, whether or not Defendant was *required* to list the weight or measure on the Principal Display Panel.

The Court's error is best shown by its finding on Dkt. 44, page 9. There, the Court wrote:

> "Without more, this would be convincing. However, the FDA's interpretation of the qualifying language in 21 C.F.R. § 101.105(c), evinced by warning letters issued to ostensible violators of 21 C.F.R. § 101.105, shows that a failure to 'give adequate information as to the quantity of food in [a] package' arises in situations involving incomparable products."

This passage, and the surrounding text show that the Court analyzed this case from the perspective of whether or not Defendant had an *obligation* to disclose the quantity (weight or measure) of the supplements at issue in this case. That, simply put, is not the claim in this case, nor is it the basis for Plaintiff's lawsuit. As discussed below, it may well be the case that Defendant had no obligation to disclose the weight or measure of its supplements on the Principal Display Panel. Plaintiff's claim is not based on the failure to disclose - instead, they are based on an inaccurate and misleading disclosure.

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2. Defendant violated the FDA regulations when it decided to include - on its Principal Display Panel - a statement of the number of units (i.e. 60 soft chews) AND THEN pair that with an *inaccurate statement* of the quantity of supplement contained in each of those units (i.e. 1000 mg).

As above if defendant had simply listed, for example, 60 soft chews and nothing else on its Principal Display Panel for its calcium supplement, it would probably not have violated the FDA's labeling regulations. Instead - presumably to gain a marketing advantage - it undertook to do more, and through an inaccurate statement of weight or measure created a misleading statement of the amount of dietary supplement per unit in its package.

The beginning point is the definition of the "net quantity of contents," cited in Defendant's briefing (Dkt. 38-1, p. 2 of 4), citing 21 CFR 101.105(a):

> "The net quantity of contents statement for a dietary supplement is the statement that informs consumers of *the amount of dietary supplement that is in the container or package.*" (Italics added.)

Defendant decided to make use of the FDA's regulations (Public Law 102329, August 3, 1992 and 21 CFR 101.105) that allowed it to:

> "express the net quantity of contents statement in either weight, measure, numerical count, *or a combination of numerical count and weight or measure.*" (Italics added.)

Because Defendant decided to go beyond just numerical count, and opted for the allowable combination of numerical count (60 soft chews) and weight or measure (1000 mg), and because that statement of weight or measure was misleading and inaccurate[1],

1 An accurate statement for the calcium product would have been "60 soft chews" and "500 mg."

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Defendant violated the FDA regulations. Because of that, Defendant's attempt to then "take back" this misstatement in fine print on the back side of its labels is unconscionable.

3. In the alternative, Plaintiff asks that this Court stay this matter, and allow the question at issue to be submitted to the FDA for determination.

In its briefing, Defendant urges the Court that because the question at issue is solely within the purview of a regulatory agency, here the FDA, it would be appropriate to submit the matter at issue to the FDA for determination. See, Dkt. 37, p. 9 where Defendant writes:

> "Thus, courts in this District and Circuit have dismissed or stayed actions that involve questions solely within the purview of a regulatory agency such as the FDA. *Verizon Nw., Inc. v. Portland Gen. Elec. Co.*, 2004 WL 97615, at *4 (D.Or. Jan.13, 2004) (granting a stay under the primary jurisdiction doctrine and noting "primary jurisdiction is concerned with overlapping issues, rather than with exact parallelism in the nature of the pending claims or the available relief" and that "under primary jurisdiction principles, a district court may defer to an agency's adjudication even if certain ultimate issues relevant to the federal court claims will remain unresolved despite the agency's decision"); *Saubers v. Kashi Co.*, --- F. Supp. 2d ----, 2014 WL 3908595, at 3 (S.D. Cal. Aug. 11, 2014) (dismissing action over labeling of "evaporated cane juice" product because "the FDA's articulation of its considered view on this matter will undoubtedly affect issues being litigated in this action"); *Hood v. Wholesoy & Co.*, 2013 WL 3553979, at 5-6 (N.D. Cal. July 12, 2013) (dismissing plaintiffs' claims because the FDA's position was unsettled). Here, Plaintiff seeks the resolution of an issue (i.e., whether subsection (c) of 21 C.F.R. § 101.105 should apply to the labeling of the Accused VS Products) over which the FDA has "statutory and comprehensive regulatory authority."

In the alternative, Plaintiff requests that this Court stay this action, and allow the question of whether Defendant's Principal Display Panels for the accused products violated the FDA regulations be submitted to the FDA for determination. If the FDA agrees with Defendant, then dismissal of claims supported by Plaintiff's interpretation

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and application is proper. If the FDA agrees with Plaintiff, then the case can be removed from stay, and proceed accordingly.

CONCLUSION

Plaintiff's complaint and claims are not based on Defendant's *failure to disclose* the quantity (weight and measure) of its supplements on the Principal Display Panels. Instead, this case is about Defendant making the conscious decision to include the quantity on the Principal Display Panels, and doing so in a misleading and inaccurate manner.

The Court below erred when it dismissed this case on the basis that Defendant had no obligation to disclose the quantity of its supplements on its Principal Display Panels. That may well be the case. This case is instead based on Defendant's inaccurate statements.

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The Court's dismissal should be overturned, and this case should proceed. In the alternative, this case should be stayed, and the matter at issue submitted to the FDA for determination.

Dated: May 27, 2015.

Rick Klingbeil, PC

/s/ Rick Klingbeil

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